

भारतीय मानक मसौदा  
मैंगनीज कार्बोनेट — विशिष्टि  
(IS 11237 का पहला पुनरीक्षण)

*Draft Indian Standard*  
**Manganese Carbonate — Specification**  
(*First Revision of IS 11237*)

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ICS 71.060.50

Inorganic Chemicals Sectional Committee, CHD 01

Last date of comments: 9<sup>th</sup> December 2024

Inorganic Chemicals Sectional Committee, CHD 01

FOREWORD

*(Formal clauses will be added later)*

This standard was originally published in 1985. In this revision, instrumental test method for the determination of iron, calcium, sulphates and chlorides have been added as alternate test method. In addition to this, editorial corrections have been made wherever required. Also, Reference clause has been incorporated. Further, Packing and Marking clause has been updated.

Manganese carbonate is used in the manufacture of manganese salts, medicine, paint pigment, fertilizers and in food additives.

This standard does not cover manganese carbonate used as food additives, fertilizer and in pharmaceutical preparations.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 2022 'Rules for rounding off numerical values (*second revision*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

*Draft Indian Standard*  
**MANGANESE CARBONATE — SPECIFICATION**  
*(First Revision)*

**1 SCOPE**

This standard prescribes the requirements and methods of sampling and test for manganese carbonate.

**2 REFERENCES**

The standards given below contain provisions which, through reference in this text, constitute provision of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent edition of these standards:

<i>IS No.</i>	<i>Title</i>
IS 264 : 2005	Nitric acid — Specification ( <i>third revision</i> )
IS 265 : 2021	Hydrochloric acid — Specification ( <i>fifth revision</i> )
IS 1070 : 2023	Reagent grade water — Specification ( <i>fourth revision</i> )
IS 3025 (Part 2) : 2019/ISO 11885 : 2007	Methods of sampling and test (physical and chemical) for water and wastewater Determination of selected elements by inductively coupled plasma optical emission spectrometry (ICP - OES) ( <i>first revision</i> )
(Part 65) : 2022/ISO 17294-2 : 2016	Application of Inductively Coupled Plasma Mass Spectrometry (ICP-MS) — Determination of selected elements including Uranium Isotopes ( <i>first revision</i> )
IS 4905 : 2015/ ISO 24153 : 2009	Random sampling and randomization procedures ( <i>first revision</i> )

**3 REQUIREMENTS****3.1 Description**

The material shall be in the form of light brown to brown homogeneous powder. It shall be free from foreign matter.

**3.2** The material when tested as prescribed in Annex A shall also comply with the requirements given in Table 1. Reference to relevant clauses of Annex A is given in col 4 of Table 1.

**4 PACKING AND MARKING****4.1 Packing**

The material shall be packed in polyethylene laminated jute bags or as agreed to between the purchaser and the supplier.

**Table 1 Requirements for Manganese Carbonate**

*(Clause 3.2)*

Sl No.	Characteristic	Requirement	Method of Test (Ref to Cl No. In Annex A)
(1)	(2)	(3)	(4)
i)	Assay ( as $\text{MnCO}_3$ ),	92.0	A-2

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	percent by mass, <i>Min</i>		
ii)	Nitric acid in solubles, precent by mass, <i>Max</i>	0.15	<b>A-3</b>
iii)	Alkali carbonates ( as Na <sub>2</sub> CO <sub>3</sub> ), percent by mass, <i>Max</i>	0.01	<b>A-4</b>
iv)	Chlorides ( as Cl ), percent by mass, <i>Max</i>	0.1	<b>A-5 or A-10</b>
v)	Sulphates ( as SO <sub>4</sub> ), percent by mass, <i>Max</i>	2.5	<b>A-6 or A-10</b>
vi)	Calcium ( as Ca ), percent by mass, <i>Max</i>	0.2	<b>A-7 or A-9</b>
vii)	Iron ( as Fe ), percent by mass, <i>Max</i>	0.1	<b>A-8 or A-9</b>

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#### 4.2 Marking

Each package shall bear legibly and indelibly the following information:

- Name of the material;
- Name of the manufacturer and his recognized trade-mark, if any;
- Gross and net mass;
- Date of manufacture; and
- Batch number.

##### 4.2.1 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the products may be marked with the standard mark.

#### 5 SAMPLING

The method of drawing representative samples of the material and the criteria for conformity shall be as prescribed in Annex B.

## ANNEX A

(Clause 3.2)

## METHOD OF TEST FOR MANGANESE CARBONATE

## A-1 QUALITY OF REAGENTS

Unless specified otherwise, (*see* IS 1070) shall be used pure chemicals and distilled water in tests.

NOTE — 'Pure chemicals' shall mean chemicals that do not contain impurities which affect the results of analysis.

## A-2 ASSAY

## A-2.1 Reagents

A-2.1.1 *Concentrated Nitric Acid* — *see* IS 264.

A-2.1.2 *Sodium Bismuthate* — powder.

A-2.1.3 *Ferrous Ammonium Sulphate Solution* — 0.1 N (approximately).

A-2.1.4 *Standard Potassium Permanganate Solution* — 0.1 N.

## A-2.2 Procedure

Weigh accurately about 1 g of the sample into a 250 ml volumetric flask containing about 50 ml of water and dissolve it therein by slowly adding 5 ml of nitric acid. When solution is complete make up to 250 ml with water. Transfer 25 ml of it to 500 ml iodine flask containing an ice cooled mixture of 75 ml of water and 20 ml of nitric acid, add 1.5 g of sodium bismuthate and shake gently for 2 to 3 minutes. Dilute with 100 ml of water washing down the sides and filter through a sintered glass funnel. Wash the flask and funnel with minimum quantity of nitric acid diluted with 33 volumes of water until the washing is colourless. To the filtrate and washings collected in a 500 ml conical flask, add 50 ml of ferrous ammonium sulphate and titrate the excess of it with standard potassium permanganate. Find out the blank reading by titrating 50 ml of the ferrous ammonium sulphate mixed with a cooled mixture of 100 ml of water and 20 ml of nitric acid with standard potassium permanganate solution.

## A-2.3 Calculation

$$\text{Assay ( as MnCO}_3 \text{ ), percent by mass} = \frac{(V_1 - V_2) \times N \times 23}{M}$$

where

$V_1$  = volume in ml of standard potassium permanganate solution required for the blank;

$V_2$  = volume in ml of standard potassium permanganate solution required for sample;

$N$  = normality of standard potassium permanganate solution, and

$M$  = mass in g of the material taken for the test.

## A-3 NITRIC ACID INSOLUBLES

## A-3.1 Reagents

A-3.1.1 *Dilute Nitric Acid* — 20 percent (*m/v*).

## A-3.2 Procedure

Dissolve 5 g of the sample in 100 ml of dilute nitric acid, filter, wash the insoluble residue with hot water till filtrate is free from acid and ignite in a tared crucible and weigh to constant mass.

## A-3.3 Calculation

$$\text{Nitric acid insolubles, percent by mass} = M \times 20$$

where

$M$  = mass in g of the residue + crucible.

## A-4 ALKALI CARBONATE

**A-4.1 Reagents**

**A-4.1.1** *Standard Hydrochloric Acid* — 0.02 N.

**A-4.2 Procedure**

Boil 2 g of the sample with 30 ml of water, filter, wash with 20 ml of hot water and cool. Any pink colour produced in the filtrate when 2 drops of phenolphthalein are added should not require more than 0.2 ml of standard hydrochloric acid to discharge it.

**A-5 CHLORIDES****A-5.1 Reagents**

**A-5.1.1** *Dilute Nitric Acid* — 30 percent (v/v).

**A-5.1.2** *Silver Nitrate Solution* — 10 percent (m/v).

**A-5.1.3** *Standard Chloride Solution*

Dissolve 0.1649 g of ignited sodium chloride in 1 000 ml of water. Dilute 10 ml of the solution to 100 ml. One millilitre of the diluted solution is equivalent to 0.01 mg of chloride (as Cl).

**A-5.2 Apparatus**

**A-5.2.1** *Nessler Cylinder* — 50 ml capacity.

**A-5.3 Procedure**

Dissolve 1 g of the sample in 20 ml of dilute nitric acid, filter and make up to 100 ml. To 5 ml of it, taken in a Nessler cylinder, add 3 drops of silver nitrate solution, dilute and mix well. Any turbidity produced should be not greater than that produced in a control where 5 ml of standard chloride solution containing 0.01 mg of chloride per ml were acidified with 1 ml of dilute nitric acid and treated in a similar manner.

**A-5.4** Chlorides may alternatively be determined by instrumental test method as prescribed at **A-10**.

**A-6 SULPHATES****A-6.1 Reagents**

**A-6.1.1** *Hydrogen Peroxide Solution* — 30 percent.

**A-6.1.2** *Hydrochloric Acid* — see IS 265.

**A-6.1.3** *Dilute Hydrochloric Acid* — 10 percent (v/v).

**A-6.1.4** *Barium Chloride Solution* — 10 percent (m/v).

**A-6.1.5** *Standard Sulphate Solution*

Dissolve 1.48 g of ignited sodium sulphate ( $\text{Na}_2\text{SO}_4$ ) in water and dilute to 1 000 ml. Take 10 ml of this solution and dilute to 100 ml. One millilitre of this solution contains 0.1 mg of sulphate (as  $\text{SO}_4$ ).

**A-6.2 Procedure**

To 5 g of the sample in a 250 ml beaker, add 25 ml of water, 2 ml of hydrogen peroxide and heat on a steam bath for 15 minutes. Add 15 ml of hydrochloric acid, evaporate to dryness on a steam bath, dissolve the residue in 40 ml of water and 1 ml of hydrochloric acid, filter if necessary and dilute to 100 ml in a volumetric flask Dilute 10 ml of this to 100 ml and preserve the rest.

**A-6.3** To 2 ml of the above diluted solution transferred into a 50 ml Nessler cylinder add 1 ml of 10 percent hydrochloric acid followed by 2 ml of barium chloride solution, stir well. Any turbidity produced should not be greater than that produced in a control where 0.25 mg of sulphate is treated in a similar manner.

**A-6.4** Sulphates may alternatively be determined by instrumental test method as prescribed at **A-10**.

**A-7 CALCIUM****A-7.1 Reagents**

**A-7.1.1 Ammonium Chloride Solution** — 11 percent (m/v).

**A-7.1.2 Dilute Ammonia Solution** — 10 percent (v/v).

**A-7.1.3 Standard Calcium Solution**

Weigh 0.25 g of calcium carbonate dried at 120 °C and dissolve it in the minimum quantity of dilute hydrochloric acid. One millilitre of the solution is equivalent to 0.1 mg of calcium (as Ca).

**A-7.1.4 Ammonium Oxalate Solution** — 4 percent (m/v).

## **A-7.2 Procedure**

To 2 ml solution from **A-6.1**, transferred into a 100 ml beaker and diluted with 10 ml of water, add 2 ml of ammonium chloride ( 11 percent ) followed by 10 ml ( or more if necessary ) of dilute ammonia and 7 ml of dilute hydrogen peroxide ( 1:6 ) with stirring. Boil to complete the precipitation, filter and wash the precipitate into a 50 ml Nessler cylinder where it is cooled to room temperature. Add 4 ml of ammonium oxalate solution (4 percent dilute to 50 ml, stir with a glass rod and let it stand for 20 min. Any turbidity produced should be not greater than that produced in a control where 0.2 mg of freshly prepared calcium were treated with 2 ml of ammonium chloride, 2 ml of dilute ammonia and 4 ml of ammonium oxalate in 10 ml volumes 20 min earlier.

## **A-8 IRON**

### **A-8.1 Reagents**

**A-8.1.1 Concentrated Hydrochloric Acid** — see IS 265.

**A-8.1.2 Butanolic Potassium Thiocyanate Solution**

Dissolve 10 g of potassium thiocyanate in 10 ml of water. Add sufficient *n* butanol to make up to 100 ml and shake vigorously until the solution is clear.

**A-8.1.3 Standard Iron Solution**

Dissolve 0.702 g of ferrous ammonium sulphate [ $\text{FeSO}_4(\text{NH}_4)_2 \cdot \text{SO}_4 \cdot 6\text{H}_2\text{O}$ ] in water and add 10 ml of concentrated hydrochloric acid and dilute with water to 1 000 ml. One millilitre of the solution is equivalent to 0.1 mg of iron (as Fe).

### **A-8.2 Procedure**

To 0.5 ml from **A-6.1** into a test tube add 10 ml of water, 1 ml of hydrochloric acid followed by 15 ml of butanolic potassium thiocyanate solution. Shake well. The red colour produced in the butanolic layer should not be more than 5 ml of standard iron solution prepared as under when treated as per the aliquot.

**A-8.2.1** Pipette 5 ml of standard iron solution containing 0.5 mg of Fe into a beaker, add 20 ml of water, 2 ml of 30 percent hydrogen peroxide and heat in a steam bath for 15 min. Add 15 ml of hydrochloric acid and evaporate to dryness. Dissolve the residue in 40 ml of water and 1 ml of HCl. Filter if necessary and dilute to 100 ml. Take 5 ml of this standard solution and treat as the aliquot.

### **A-8.3 Alternative Method**

Iron may alternatively be determined by ICP-OES instrumental test method as prescribed at **A-9** or ICP-MS method as prescribed in IS 3025 (Part 65).

Instrumental test method using ICP-OES or ICP-MS shall be used as referee method in case of any dispute.

## **A-9 DETERMINATION OF IRON BY INDUCTIVELY COUPLED PLASMA OPTICAL EMISSION SPECTROMETER (ICP-OES) METHOD**

### **A-9.1 Principle**

The sample solution under analysis is nebulized through a nebulizer inside a spray chamber. The aerosol formed is aspirated to argon plasma torch [produced by a radio-frequency inductively coupled plasma (ICP)], where the molecules break into constituent atoms and/or molecular species and atoms are get excited. These excited atoms then return back to the lower energy state by emitting radiation of specific wavelength. These emitted radiations are

characteristic of an element and are measured by the Photomultiplier tube detector and intensity of such emitted radiation is directly proportional to the concentration of respective constituent element in the sample.

### A-9.2 Recommended Wavelength, limit of quantification and important spectral interferences

Elements along with the recommended wavelengths and typical estimated limits of quantification are listed in Table 2. Actual working detection limits are dependent on the type of instrumentation, detection device and sample introduction system used and on the sample matrix. Therefore, these concentrations can vary between different instruments.

Additionally, Table 2 lists the most important spectral interferences at the recommended wavelengths for analysis.

**Table 2 Recommended Wavelengths, Achievable Limits of Quantification for Different Configuration of Instruments and Important Spectral Interferences**

(Clauses A-9.2 and A-9.4)

Sl No.	Element	Wavelength (nm)	Approximately Achievable Limits		Interfering Elements
			Radial Viewing (µg)	Axial Viewing (µg)	
(1)	(2)	(3)	(4)	(5)	(6)
i)	Fe	238.204	14	(3)	Co
		259.940	6	2	Co
		271.441	-	-	-
ii)	Ca	315.887	100	13	Co, Mo
		317.933	26	4	Fe, V
		393.366	0.4	25	V, Zr
		422.673	-	-	V, Mo, Zr

### A-9.3 Reagents and Solutions

#### A-9.3.1. Nitric Acid (65 percent) Suprapure

#### A-9.3.2 Standard Stock Solution

Either prepare by dissolving proportionate amount of soluble compounds of elements (preferably spectroscopic grade), or use commercially available certified stock solution of 10, 100 or 1 000 µg/ml of Lead, Iron, calcium, magnesium, manganese, arsenic, molybdenum, aluminium and mercury in 2 to 5 percent nitric acid. It is preferable to prepare single stock solution of multi elemental standards for analysis.

#### A-9.3.3 Standard Solution

Pipette out 5 ml from 100 µg/ml standard stock solution into a 100 ml volumetric flask and make up volume with 2 percent nitric acid to prepare 5 µg/ml solution. From this 5 µg/ml solution, an aliquot of 1.0, 3.0 and 5.0 ml taken in 50 ml volumetric flasks (separate) and make up volume with 2 percent nitric acid to prepare 0.1, 0.3 and 0.5 µg/ml solution of respective elements under reference.

#### A-9.3.4 Sample Preparation

Weigh about 2.5 g of the sample in a 50 ml volumetric flask and add 1.0 ml nitric acid and make up the volume with water.

NOTE — Sample should be clear before injecting to the instrument.

#### **A-9.3.5 Reagent Blank Solution**

Place 50 ml of nitric acid and 1 000 ml of water into an HDPE or PP container. For ultra-trace analysis, polytetrafluoroethylene (PTFE) containers should be used. Prior to analysis, make sure that the acid matrix and concentration of the reagent blank solution is the same as in the standard and sample solutions.

#### **A-9.4 Instrument**

Set up the instrument as per the manufacturer's instructions manual for recommended operating parameters, based on the manufacturers operating manual and evaluated by internal check analysis using of standard solution of element as well as data selected carefully from Table 2.

For analysis of mercury and arsenic, a gas (hydride)/vapour generating system is coupled with ICP, instead of using of nebulizer. The mercury vapour/arsine generated through the system is carried by the carrier gas (Ar) to plasma torch, and other instrumental conditions shall be the same as above.

NOTE — Sensitivity, instrumental detection limit, precision, linear dynamic range and interference effects will be investigated and established for each individual analyte line on that particular instrument.

#### **A-9.5 Procedure**

##### **A-9.5.1 Calibration**

Profile and calibrate the instrument according to the instrument manufacturer's recommended procedures, using the intermediate mixed standard solutions (A-9.3.5). The relationship between concentration and intensity is linear up to six orders of magnitude. Examine the spectra of the element and make necessary adjustments (if required) for the exact peak positions and baselines to ensure proper measurements of the respective peak intensities. Flush the system with the reagent blank solution between each standard.

**A-9.5.2** Before beginning the sample run, re-analyse the reference standard with the highest concentration as if it were a sample. Ensure that the concentration values do not deviate from the actual values by more than  $\pm 5$  percent (or the established control limits, whichever is lower). If they do, follow the recommendations of the instrument manufacturer to correct for this condition. Begin the sample run by flushing the system with the reagent blank solution between each sample. It is recommended to analyse a calibration check solution and the calibration blank solution every 10 samples. Analyze the sample solution and calculate the concentration in  $\mu\text{g/ml}$  of the lead (and/or Iron, arsenic) in the sample solution.

NOTE — It is recommended that IS 3025(Part 2) /ISO 11885 may be referred and practiced for ensuring precise and reproducible analysis.

#### **A-9.6 Calculation**

The mass concentrations for each element are determined with the aid of the instrument software by following steps.

- i) Relate emission signals from calibration blank and calibration solutions with the signals from reference elements and establish a calibration plot.
- ii) Determine the mass concentrations of samples with the aid of the emissions and the calibration graphs and calculate the quantity in  $\text{mg/kg}$  of the constituent elemental impurities in the sample, by multiplying the value by 20 (Dilution factor).

### **A-10 ION CHROMATOGRAPHY FOR CHLORIDES AND SULPHATES**

#### **A-10.1 Principle**

Ion Chromatography is an innovative method for the determination of ions. The technique is used for the analysis of chlorides and sulphates. The technique separates ions and polar molecules based on their affinity to ion exchanger. When the method is employed for the determination of the anions as chlorides and sulphates, the identification should be made by using a matrix covering the ions of interest. In cation exchange chromatography, the stationary phase is functionalized with anions. These anions will attach cations towards it. These surface bound molecules/ionic species



can then be removed by using a suitable eluent containing substituted ions to replace them or they can be removed by changing the  $pH$  of the column. Similarly, in anion exchange chromatography, the stationary phase is cationic in nature. These cations will then separate the anions.

Conductivity detector is generally used in this method. In case of suppressor ion exchange chromatography, analyte ions are separated on the ion exchange column and these ions together with the eluent move to the matrix suppressor. The eluent conductivity is lowered in the suppressor and the sample ion conductivity is increased leading to the large increase in signal to noise ratio.

### **A-10.2 Equipment**

**A-10.2.1 Anion Guard Column** — a protector of the separator column

**A-10.2.2 Anion Separator Column** — suitable for selective separation of ions under analysis.

**A-10.2.3 Anion Suppressor Device**

Anion micro membrane suppressor is used to analyse the data

**A-10.2.4 Detector** — conductivity detector

**A-10.2.5 Software**

Software suitable for control of various operating parameters, receiving inputs and analysis of all data

**A-10.2.6 Sample loop** of 100  $\mu$ l, 200  $\mu$ l, 500  $\mu$ l or 1 000  $\mu$ l be used to determine ionic concentration as per instrument manual and practice.

### **A-10.3 Reagents**

**A-10.3.1 Glass or Polyethylene Sample Bottles.**

**A-10.3.2 Distilled Water or Deionized Water free from the Anions of interest.**

**A-10.3.3 Eluent**

1.7 mM of sodium bicarbonate and 1.8 mM of sodium carbonate solution is used. For preparation of these solution, 0.285 6 g of sodium bicarbonate and 0.381 6 g of sodium carbonate is dissolved in 2 litre of water.

**A-10.3.4 Micro membrane suppressor solution: (0.025 N of sulphuric acid)**

Dilute 2.8 ml of concentrated sulphuric acid in 4 litre of water

### **A-10.4 Standard solutions**

**A-10.4.1 Chloride**

Dissolve NaCl, 1.648 5 g in 1 000 ml of reagent water

**A-10.4.2 Sulphate**

Dissolve 1.81 g of potassium sulphate in 1 000 ml of reagent water

### **A-10.5 Calibration and Standardization**

For each analyte of interest, prepare calibration standards at three concentration levels and a blank by adding measured stock standards and diluting with reagent water. If the concentration of the sample exceeds the calibration range, the sample may be diluted. Using 0.1 ml to 1.0 ml injections of each calibration standard, tabulate area responses or peak height against the concentration. Use these results to prepare calibration curve. Record the retention time during the procedure.

### **A-10.6 Procedure**

Dissolve between 1 g to 5 g samples in 25 ml reagent grade water in PTTE/HDPE beaker and use this solution for analysis. Inject a well-mixed sample (0.1 ml to 1.0 ml) and flush it through an injection loop using each new sample.

Use the loop of same size for the standards and samples. Record the peak in size and area units. An automated constant volume injection system may preferably be used. The width of peak for retention time of ions should be same for sample and standard. Dilute the sample with the help of reagent water if the response for the peak exceeds the working range of the system for analysis. If required, spike the sample with an appropriate amount of standard and reanalyze in case of absence of distinct resolution. Retention time is inversely proportional to concentration. For solid sample of cobalt acetate, following extraction procedure may be used.

Add reagent water in an amount equal to 10 times the dry weight of the sample. The slurry is made and stirred for about 10 min using magnetic stirrer. This slurry is filtered from 0.45  $\mu$  membrane. This membrane can be directly attached to the end of the syringe. For clear resolution, the sample can further be diluted. The dilution should be made to an extent till there is no deviation from the method.

#### **A-10.7 Data analysis and Calculations**

Prepare a calibration curve for each analyte by plotting instrument response against concentration. Compare the sample response with the standard curve and compute sample concentration. Multiply the value by appropriate dilution factor.

Report results in mg/l or by suitably modifying into percentage. Only report those values that fall within the range of lowest and highest calibration standards.

### **ANNEX B**

*(Clause 5.1)*

#### **SAMPLING OF MANGANESE CARBONATE**

##### **B-1 GENERAL REQUIREMENTS OF SAMPLING**

**B-1.1** In drawing, preparing, storing and handling test samples, the following precautions and directions shall be observed.

**B-1.2** Samples shall not be taken at the place exposed to adverse effects of weather.

**B-1.3** The sampling instruments and sample containers shall be clean and dry.

**B-1.4** Precautions shall be taken to protect the samples, the material being sampled, the sampling instrument and the containers for samples from adventitious contamination.

**B-1.5** To draw a representative sample, the contents of each container selected for sampling shall be mixed as thoroughly as possible by suitable means.

**B-1.6** The samples shall be placed in clean, dry and airtight glass or other suitable containers on which the material has no action.

**B-1.7** The sample containers shall be of such a size that they are almost completely filled by the sample.

**B-1.8** Each sample container shall be sealed airtight after filling and marked with full details of sampling the date of sampling and the lot and batch numbers.

##### **B-2 SCALE OF SAMPLING**

###### **B-2.1 Lot**

All the containers in a single consignment of the material drawn from the same batch of manufacture shall constitute a lot. If a consignment is declared or known to consist of different batches of manufacture the containers belonging to the same batch shall be grouped together and each such group shall constitute a separate lot.

**B-2.2** Samples shall be tested for each lot for ascertaining the conformity of the material to the requirements of this specification.

**B-2.3** The number of containers (*n*) to be chosen from a lot shall depend upon the size of the lot (*N*) and shall be in accordance with Table 3.

**Table 3 Number of Containers to be Selected for sampling**

(Clause B-2.3)

SI No (1)	Lot Size (2)	Sample Size (3)
i)	Up to 50	3
ii)	51 to 100	4
iii)	101 to 150	5
iv)	151 to 300	7
v)	301 and above	10

**B-2.4** These containers shall be chosen at random from the lot. In order to ensure the randomness of selection, reference may be made to IS 4905.

**B-3 NUMBER OF TESTS**

**B-3.1** Test for the determination of assay shall be conducted on individual sample.

**B-3.2** Test for the determination of all other characteristics given in Table 1 shall be conducted on composite sample.

**B-4 CRITERIA FOR CONFORMITY**

**B-4.1 For Individual Sample**

From the test results, the average and the range shall be calculated as follows:

$$\text{Average} = \frac{\text{Sum of the test results}}{\text{Number of tests}}$$

Range = The difference between the maximum and the minimum values of the test results.

The lot shall be declared as conforming to the requirements of assay if  $X - 0.6 R$  is greater than the minimum value specified.

**B-4.2 Composite Sample**

For declaring the conformity of the lot to the requirements of all other characteristics tested on the composite sample, the test result for each characteristic shall satisfy the relevant requirements given in Table 1.